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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,289	08/10/2000	Volker Landschutze	514413-3834	7068
20999	7590	07/01/2004	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/636,289	Applicant(s) LANDSCHUTZE, VOLKER	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004 and 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-12,15,19,22-24,29,31 and 33-37 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-12,15,19,22-24,29,31 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 April 2004 has been entered. In addition, the amendment of 15 March 2004 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 15 March 2004 have overcome all claim objections except as indicated below, and all indefiniteness rejections of record.

The application should be reviewed for errors. Errors appear, for example, in claim 2, part (a), line 3, where "encode" should be replaced with ---encodes---; and in claim 36, line 5 where "molecule leads" should be replaced with ---molecules lead---.

Claims 2, 7, 12, 15, 19, 22-24, 29, 31 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in the rejections.

Claim 2 is indefinite in its recitation in part (c) of "DNA molecule which encodes at least one antisense RNA...and which encodes at least one sense RNA" which is confusing, in its implication that a DNA encodes a sense and antisense RNA simultaneously. If intended, the following amendments would obviate this rejection:

In claim 2, part (c), line 2, delete "and".

In claim 2, part (c), line 3, delete "which encodes at least one sense RNA".

In claim 2, part (c), line 3, insert after "molecule" the following:

---which encodes at least one sense RNA and---

Claim 15 is indefinite in its recitation of "potato plant as claimed in claim 1" since "plant" lacks antecedent basis in claim 1, which is drawn to plant cells. The following amendment would obviate this rejection:

---Claim 15 (currently amended). A reproductive material of a potato plant, wherein said reproductive material comprises potato plant cells as claimed in [claim 1] claims 1 or 2.---

Claims 1-2, 7-12, 15, 19, 22-24, 29, 31 and 33-37 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 3 of the final Office action mailed 13 January 2004.

Claims 1-2, 7-12, 15, 19, 22-24, 29, 31 and 33-37 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to nucleic acid constructs comprising at least 1330 base pairs of the potato GBSSI gene and the entire coding sequence of the potato BEI gene, each in antisense or sense orientation with respect to its own promoter, does not reasonably provide enablement for claims broadly drawn to plant transformation with a single gene

encoding a single antisense RNA or a single sense RNA which somehow reduces the expression or activity of both GBSSI and BEI, genes which encode or reduce the expression of any type of BE (claim 1), or a single gene encoding both GBSSI and BEI (claim 1, part a). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 3-4 of the final Office action mailed 13 January 2004.

The claims remain free of the prior art, as stated on page 2 of the final Office action of 13 January 2004.

No claim is allowed.

Applicant's arguments filed 15 March 2004 have been fully considered but they are not persuasive. Applicant urges that the written description and enablement rejections are improper, given the assertions in the Landschutze declaration filed 15 March 2004 that the skilled artisan can choose any nucleic acid sequences from any plant which would exhibit the claimed effects on the expression of endogenous GBSSI and BE genes, including the use of cosuppression via sense sequences, GBSSI and BE genes from plants other than potato, any sequence with about 65% homology to the endogenous GBSSI and BE genes, or untranslated 5' or 3' regions.

The Examiner maintains that an opinion declaration by Applicant is insufficient to rebut the evidence and scientific reasoning provided by the Examiner to support his position.

See *Voisnet v. Coglianese and McCorkle*, 173 USPQ 16 (CCPA 1972), which teaches that the opinion testimony of an expert witness does not establish any material fact and may be rejected in favor of other evidence.

As stated previously, regarding written description, the disclosure of a single species for each of the two broadly claimed genera provides insufficient evidence that Applicant was in possession of the claimed invention at the time it was made. Applicant discloses and describes a single species of at least 1330 base pairs of the potato GBSSI gene to represent the genus of sequences which somehow inhibit the expression of an endogenous GBSSI gene. Applicant discloses and describes a single species of the entire potato BEI gene to represent the genus of sequences which somehow inhibit the expression of an endogenous BE gene. Applicant does not identify any sequence within either of these species which is conserved throughout the broadly claimed genus of any sequence which somehow reduces GBSSI activity, any sequence which somehow reduces BE activity, or any sequence which somehow reduces the expression of both GBSSI and BE genes simultaneously, as claimed in part (a) of claim 1, for example. Thus, Applicant fails to meet either prong of the two-prong test of *Lilly* cited previously: 1) a representative number of sequences and 2) the correlation of sequence with function.

Regarding enablement, Applicant is directed to Kull et al and Kuipers et al cited on pages 8 and 9 of the first Office action mailed 21 May 2002. Kull et al clearly teach that antisense GBSSI sequences *from barley* had no effect on the starch produced by *potato plants* transformed therewith (see paragraph bridging pages 8 and 9 of the first

Office action). Kuipers et al teach that a nucleic acid construct which reduced the expression of a single enzyme, namely GBSS, had no effect on the expression of any other enzyme (see first full paragraph on page 9 of the first Office action). Thus, the Examiner has provided publications which refute Applicant's mere assertions that any sequence from any plant would work, or that any sequence which does not correspond to the targeted gene would work.

Furthermore, while Applicant argues that any BE or GBSSI gene from any plant would be able to inhibit the expression of endogenous BE or GBSSI genes, it is noted that the claims are not limited to inhibitory sequences comprising BE or GBSSI genes, as stated above.

Regarding the issue of sense suppression (or "co-suppression"), the Examiner now considers that undue experimentation would not have been required by one skilled in the art to obtain cosuppression when utilizing the same exemplified gene fragments utilized by Applicant for antisense suppression. However, undue experimentation would have been required to evaluate a multitude of non-exemplified sequences and sequence fragments of any length and from any source for their ability to achieve sense suppression of endogenous BEI and GBSSI genes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

June 24, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

